Proposed Guidance on Plant Biostimulants

Plant Biostimulants (PBS)

- New, growing category of agricultural products
- Comprised of naturally-occurring substances and microbes
- Stimulate plant growth via improved nutrient and water use efficiency, protection from abiotic stress, and/or plant regulator activity
- Not considered to be fertilizers or to be used for pest control
- Reduce use of synthetic agricultural chemical fertilizers
- (DuJardin, 2015; Craggs, 2017)
- Attractive for sustainable agriculture and IPM programs

(Russo & Berlyn, 1990; Velez & Kloepper, 2014)

Plant Biostimulants (PBS) Market

- Global market expected to reach over $4.49 billion by 2025*
- Estimated compound growth rate of 13.2% over the next decade*
- North American market expected to reach $766 million by 2022**
- North America is second largest global market**

* Global Plant Biostimulants Market (Business Wire-May 4, 2017)

** North America Biostimulants Market: Industry Growth, Trends, & Forecasts 2017-2022 (Mordor Intelligence, December, 2017)

Plant Biostimulants (PBS) Regulatory Issues

- Some (not all) PBS may be considered plant regulators under FIFRA
- Some product label claims may be considered plant regulator claims
- FIFRA Section 2(u) defines plant regulators as pesticides
- FIFRA Section 2(v) defines plant regulators and substances excluded from definition of a plant regulator

Plant Regulator Definition under FIFRA Section 2(v)

"...any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof..."

Does not include:

- plant nutrients/nutritional chemicals
- trace elements
- plant inoculants
- soil amendments
- vitamin-hormone horticultural products [40 CFR 152.6(f)]

The proposed guidance is intended to:

- Identify examples of plant regulator claims on product labels
- Identify examples of non-plant regulator claims on product labels
- Provide clarity to regulated community and to State/Federal regulators for product claims that trigger FIFRA regulation
- Be legally non-binding

The proposed guidance does not create any new regulatory definitions

Expected Benefits/Costs once Guidance is Final

- Eliminate ambiguity and provide regulatory clarity
- Specify products and label claims that may require registration
- Reduce regulatory burden
  - Cost savings not quantifiable; as industry grows, regulatory clarity increases in value
  - Savings mostly intangible (less effort to determine appropriate regulatory path
  - Avoid delays in marketing, product recalls
  - Avoid label redesign/printing costs
- Savings for State and Other Federal Regulatory Agencies (USDA, FDA)
  - clarity on products not needing registration under FIFRA

Internal Response to Draft Guidance

- Regions 2, 3, 6, 8 and 9; ORD and OP concur on current draft
- Regions 4 and 10
  - Concur with minor wording changes
- OECA :
  - Title change and major reorganization of document requested
  - Some proposed non-plant regulator claims appeared to be the same as proposed plant regulator claims
- Regions 1, 5 and 7
  - Some proposed non-plant regulator claims appeared to be the same as proposed plant regulator claim

BPPD Action on Internal Response

- Regions 2, 3, 6, 8 and 9; ORD and OP concur on current draft: Found guidance useful No action needed
- Regions 4 and 10: Concur with minor wording changes: Changes accepted; Region 10 requested re-add of known plant regulator actives that was removed from original draft.
- OECA : Title change and major reorganization of document requested: Title change accepted; reorganization not done because document structure had already been approved by BPPD and OGC. If needed, can be done after OMB review.
  - Some proposed non-plant regulator claims appeared to be the same as proposed plant regulator claims: BPPD concurred on some claims and added qualifiers such as, improves *soil* conditions for increased plant growth/mass/yield. In other, instances, the claim was removed.
- Regions 1, 5 and 7
  - Some proposed non-plant regulator claims appeared to be the same as proposed plant regulator claim: Same as Above

Industry Perspective

- All seek clarification and guidance on products that may or may not be subject to regulation under FIFRA
- Some seek regulation under FIFRA
- Some seek third party certification of products that are not subject to regulation under FIFRA
  - Proposal to create a US Plant Biostimulants Program (oversight by USDA/AMS)
    - Certification process acceptable across all States
    - Standards and criteria
    - Registry of certified products
- Some do not want any form of Federal regulation or third party certification

US State Perspective

- State pesticide and fertilizer regulators frequently seek guidance from EPA on Plant Biostimulant products
  - Do they require registration under FIFRA?
  - Looking for EPA to provide regulatory clarity

USDA Perspective

- 2018 Farm Bill Sec. 9201. Report on Regulation of Plant Biostimulants
  - Ag Secretary to submit report *"...identifying potential regulatory and legislative reforms to ensure expeditious and appropriate review, approval, uniform national labeling, and availability of plant biostimulant products to agricultural producers."*
  - Consultation with EPA, States, Industry, and other stakeholders
    - May include development of US Plant Biostimulant Product (PBP) program
  - Proposed definition for Plant Biostimulants
    - Almost identical to proposed EU definition

International Perspective

- European Union (EU) developed a draft definition and regulatory framework for Plant Biostimulants as part of their new EU Fertilizer Regulation update
  - Still undergoing technical modifications (completion 2018?)
  - Proposed implementation 2021
- Outside of US and EU, Plant Biostimulants are:
  - Unregulated, or
  - Regulated under existing fertilizer regulations, or
  - Regulated under existing plant protection/pesticide regulations

EPA Involvement Since 2012

- **April 2012:** Informal EPA/BPPD review of "The Science of Plant Biostimulants-A Bibliographic Analysis
- **July 2014-2015:** EPA/OPP presentations on the regulation of biopesticides and plant regulators in the US at Crops & Chemicals, Raleigh, NC. Initial contacts with European Biostimulants Industry Council (EBIC) and US Biostimulants Coalition (USBC in 2015)
- **August 2015:** Presentation on registration of plant regulators and plant biostimulants to the Association of American Plant Food Control Officials (AAPFCO). Initial contacts with US Biostimulants Coalition (USBC) and Biological Products Industry Alliance (BPIA)
- **Summer 2015:** Start of guidance development for plant biostimulants by EPA
- **2015-Present:** Numerous discussions/presentations with stakeholders including: BPIA, EBIC, USBC, individual PBS distributors/manufacturers

November 2017: Presentation on PBS Guidance development to Third World Biostimulants Congress in Miami; over 700 attendees

Stakeholder Involvement Since 2014

- State and EPA Regional regulators (via the State FIFRA Issues Research and Evaluation Group (SFIREG); and informal/formal contact with Regions, ORD, OECA, and OP.
- Association of American Plant Food Control Officials (AAPFCO).
- Representatives of:
  - Biological Products Industry Alliance (BPIA)
  - European Biostimulants Industry Council
  - United States Biostimulants Coalition (USBC).
- Individual plant biostimulant producers
- Technical presentations before international audiences, such as:
  - Annual INFORMA Crops & Chemicals Biostimulants Conferences (Raleigh, NC)
  - Third World Biostimulants Congress (Miami, FL)

Table of known plant regulator active ingredients contained in current EPA-registered products.

Removed from original draft in 2016

Region 10 requested that it be added back into the Guidance

Table 3. Plant Regulator Active Ingredients Contained in EPA-Registered Products Having Modes of Action that Trigger Regulation Under FIFRA as a Pesticide [1, 2, 3]

- Abscisic Acid (ABA)
- *gamma*-Aminobutyric Acid (GABA)
- 6-Benzyladenine (6-aminopurine; a cytokinin)
- Chitin and Chitosan [4]
- Choline
- Complex Polymeric Polyhydroxy Acids (including Humic acid, fulvic acid, tannins, & organic acids from Leonardite) [5]
- Corn glutens/Corn gluten meal
- Cytokinins (as all isopentenyladenine and zeatin derivatives) [6]
- Cytokinin (as kinetin)
- Ethylene
- Gibberellic Acid A_3 (GA_3)
- Gibberellic Acid A_4/ A_7 (GA_{4+7})
- L-Glutamic Acid
- Harpin proteins [4]
- Homobrassinolide
- Indole-3 Acetic Acid (IAA)
- Indole-3-Butyric Acid (IBA)
- Jasmonates (includes all derivatives of jasmonic acid) [4]
- Lysophosphatidylethanolamine (LPE)
- Laminarin
- 1-Octanol
- Potassium silicate [4]
- *Saccheromyces cerevisiae* extract (Brewer's Yeast extract) [4]
- Salicylic Acid [4]
- Seaweed Extracts [7]
- Sodium o-nitrophenolate
- Sodium p-nitrophenolate
- Sodium guaiacolate

[1] Some EPA-registered microbial pesticides are registered as plant regulators or have plant regulator claims listed on their product labels

[2] Includes Biochemical and Microbial Induced Resistance Promoters

[3] This list only includes naturally-occurring plant regulators contained in EPA-registered products; it does not include substances under review by the Agency or known plant regulators for which no products have been proposed, but that may have plant regulator activity

[4] EPA-registered Induced Resistance Promoter

[5] Foliar applications only, soil applications may be excluded as a soil amendment in the absence of any pesticidal claims (including plant regulator claims)

[6] Isopentenyladenine derivatives are typically produced by microbes; zeatin derivatives are typically produced by plants

[7] Seaweed extracts (SWE) are heterogeneous mixtures of naturally-occurring plant regulators (Battacharyya et. al., 2015; Craigie, 2011; Stirk and Tarkowska, 2003; Stirk et. al., 2014); products containing active ingredients derived from SWE have been registered by the Agency as plant regulator products (see Appendix II)

Next Steps

- Final Agency Review (FAR): Spring 2018
- OMB Review: Summer 2018
- Public Comment: Autumn 2018
- Final Document: Winter 2018